



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0445; FRL-9915-32]

Flazasulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flazasulfuron in or on tree nut group 14-12. ISK Biosciences Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0445, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-

5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0445 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0445, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 30, 2013 (78 FR 79361) (FRL-9903-69), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3F8173) by ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077. The petition requested that 40 CFR 180.655 be amended by establishing tolerances for residues of the herbicide flazasulfuron, *N*-[[4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide, in or on tree nut group 14-12 at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Biosciences Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has added a tolerance for almond, hulls. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for flazasulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with flazasulfuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Flazasulfuron exhibits low acute toxicity via oral, dermal and inhalation routes of exposure. It is not irritating to the skin or eyes and is not a dermal sensitizer. Subchronic studies in animals indicated decreased body weight gain, slight anemia in rats, and liver abnormalities in dogs. Dermal or systemic toxicity was not seen in a subchronic dermal study in rabbits at dose levels up to the limit dose.

In the longer-term mammalian toxicity studies, the kidney and liver were the primary target organs of flazasulfuron toxicity. Observed effects included adverse changes in kidney function (chronic nephropathy) and kidney physiology (enlargement, dark color of kidney), increases in liver weight and hepatocellular hypertrophy, increases in inflammatory cell infiltration, hepatocellular necrosis, hepatocellular swelling, and bile duct proliferation.

Developmental toxicity was observed in both rats and rabbits. Reduced fetal weights and delays in ossification were seen in a developmental toxicity study with Sprague-Dawley rats; an increased incidence of visceral malformations (intraventricular septal defect) was seen in a

developmental study with Wistar rats. The developmental study in rabbits showed high incidences of abortion at the highest dose tested. Decreases in body weight and chronic nephropathy were observed in offspring in a 2-generation rat reproduction toxicity study. The effects on offspring in these studies occurred at dose levels which were also toxic to the parents.

A transient decrease in motor activity 5 hours post-dosing on Day 0 was observed at the mid-dose in an acute neurotoxicity study. This observation may be associated with a systemic effect and not with neurotoxicity since there was no corroborating indication of neurotoxicity in the subchronic neurotoxicity study. There are no indications of immunotoxicity potential from the repeated dose studies in the toxicity database. In addition, preliminary assessment of the available immunotoxicity study (currently under detailed review) shows no immunotoxicity in female mice when tested up to levels near the limit dose. Therefore, there are no concerns for immunotoxicity.

There was no evidence of carcinogenicity in the mouse oncogenicity study or the combined chronic toxicity/carcinogenicity study in the rat and no evidence of genotoxic potential in *in vitro* and *in vivo* mutagenicity studies. Based on the results of these studies, EPA has classified flazasulfuron as “no evidence of carcinogenicity to humans.”

Specific information on the studies received and the nature of the adverse effects caused by flazasulfuron as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Flazasulfuron: Human Health Risk Assessment for Proposed Uses on Tree Nuts,” at p. 28 in docket ID number EPA-HQ-OPP-2013-0445.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure

to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for flazasulfuron used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Flazasulfuron for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (General population including females, 13-49 years of age)	NOAEL = 50 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute neurotoxicity (rat) LOAEL = 1,000 mg/kg/day based on transient decrease in motor activity observed at Day 0 (5 hours post-dosing)

Chronic dietary (All populations)	NOAEL= 1.3 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.013 mg/kg/day cPAD = 0.013 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity in rats LOAEL = 13.3 mg/kg/day based on adverse change in kidney function (chronic nephropathy)
Incidental oral short-term (1 to 30 days) and Intermediate Term (1 to 6 months)	NOAEL= 2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	90-Day Oral Toxicity (dog) LOAEL = 10 mg/kg/day based on changes in liver (increase in: Deposition of brown pigments, glutamic pyruvic transaminase, creatine phosphokinase, inflammatory cell infiltration, microgranulomas)
Dermal short-term (1 to 30 days) and Intermediate-Term (1 to 6 months)	No hazard was identified at the limit dose following dermal exposure		
Inhalation short-term (1 to 30 days) and Intermediate-Term (1 to 6 months)	NOAEL= 2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF =1x	LOC for MOE = 100	90-Day oral toxicity (dog) LOAEL = 10 mg/kg/day based on changes in liver (increase in: Deposition of brown pigments, glutamic pyruvic transaminase, creatine phosphokinase, inflammatory cell infiltration, microgranulomas)
Cancer (Oral, dermal, inhalation)	Classification: No evidence of carcinogenicity to humans based on lack of carcinogenic effects in the rat and mouse carcinogenicity studies and lack of a mutagenicity concern		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day= milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flazasulfuron, EPA considered exposure under the petitioned-for tolerances as well as all existing flazasulfuron tolerances in 40 CFR 180.655. EPA assessed dietary exposures from flazasulfuron in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for flazasulfuron. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's *National Health and Nutrition Examination Survey, What We Eat in America*, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues and 100% of the crop was treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's *National Health and Nutrition Examination Survey, What We Eat in America*, (NHANES/WWEIA). As to residue levels in food, EPA made the same assumptions (tolerance level residues and 100 PCT) as in the acute dietary exposure assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flazasulfuron does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flazasulfuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flazasulfuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier II PRZM-EXAMS – Index Reservoir model and PRZM-GW model, the estimated drinking water concentrations (EDWCs) of flazasulfuron for acute exposures are estimated to be 26.9 parts per billion (ppb) for surface water and 90.8 ppb for ground water and for chronic exposures for non-cancer assessments are estimated to be 4.67 ppb for surface water and 55.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 90.8 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 55.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There are no residential uses being requested at this time. Therefore, residential handler and post-application scenarios were not assessed for the proposed tree nut use. However, there are existing residential uses that have been previously assessed and are used in the aggregate assessment presented in this document. Flazasulfuron is currently registered for the following uses that could result in residential exposures: Golf courses, sod farms, professionally managed athletic fields, commercial lawns, Christmas trees, and industrial vegetation management areas. EPA assessed residential exposure using the following assumptions:

i. *Residential Handler Exposures.* Residential short-term (1-30 days) dermal and inhalation exposures are expected from flazasulfuron handler activities associated with the residential spot treatment use. Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed. A MOE greater than 100 for the inhalation route is deemed

adequate to protect residential flazasulfuron handlers. Handler scenarios resulted in MOEs ranging from 27,000 to 6,800,000 for inhalation exposures and, therefore are not of concern.

ii. *Residential Post-application Exposures.* Since the use sites include recreational parks, there is a potential for short-term dermal and incidental oral exposures to occur for children from the broadcast use of flazasulfuron. When determining the potential for residential exposure, the Agency considers residues, leaf to skin/hand residue transfer, children's hand-to-mouth transfer, and exposure time. Since no hazard was identified for the dermal route of exposure, dermal risks were not assessed. All children post-application scenarios resulted in MOEs ranging from 2,900 to 1,300,000 for incidental oral exposures and, therefore are not of concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found flazasulfuron to share a common mechanism of toxicity with any other substances, and flazasulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flazasulfuron does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The pre- and postnatal toxicity database for flazasulfuron includes developmental toxicity studies in rats (Sprague-Dawley and Wistar) and rabbits and a 2-generation reproduction toxicity study in rats.

There was no evidence of increased quantitative susceptibility of fetuses or offspring to flazasulfuron in any of the developmental or reproductive toxicity studies, since the effects on offspring occurred at dose levels which were also toxic to the parents. There is a potential concern for increased qualitative susceptibility of offspring based on the intraventricular septal defect seen in offspring at minimally toxic maternal dose levels in the Wistar rat developmental toxicity study; however, this effect was not seen in the developmental study in Sprague-Dawley rats tested up to the limit dose, and this concern is further addressed by the presence of clear NOAELs and LOAELs, and by the selection of regulatory endpoints that are protective of this effect. Therefore, EPA has no concerns for increased qualitative susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for flazasulfuron is complete.
- ii. There is no concern for increased quantitative or qualitative susceptibility in offspring.
- iii. There are no neurotoxicity concerns.
- iv. There are no residual uncertainties regarding exposure.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flazasulfuron will occupy 3% of the aPAD for infants less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flazasulfuron from food and water will utilize 23% of the cPAD for infants less than one year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flazasulfuron is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). The short-term aggregate exposure for adults, which accounts for inhalation exposure while treating turf and dietary exposure from food and water, resulted in an MOE of 1,600 and is not of concern. The short-term aggregate exposure for children ages 1<2, which

accounts for incidental oral exposure from hand-to-mouth activities on treated turf and dietary exposure from food and water, resulted in an MOE of 810 and is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since intermediate-term residential exposures are not likely to occur, intermediate-term aggregate risks were not assessed.

5. *Aggregate cancer risk for U.S. population.* Because there was no evidence of carcinogenicity in the rat and mouse carcinogenicity studies, flazasulfuron is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to flazasulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography/tandem mass spectrometry with multiple reaction monitoring (HPLC/MS-MS/MRM) is available to enforce the tolerance expression.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an

international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for flazasulfuron.

C. Revisions to Petitioned-For Tolerances

EPA has added a tolerance for almond, hulls. Almond hulls are listed separately as a raw agricultural commodity for almonds in Table 1 of OCSPP 860.1000, and are included in Table 1 Feedstuffs (June 2008); therefore, a tolerance is required for almond hulls.

V. Conclusion

Therefore, tolerances are established for residues of flazasulfuron, *N*-[[4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(trifluoromethyl)-2-pyridinesulfonamide, in or on tree nut group 14-12 at 0.01 ppm and on almond hulls at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations

under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 27, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.655, add alphabetically the following commodities to the table in paragraph (a), to read as follows:

§ 180.655 Flazasulfuron; tolerance for residues.

(a) *General.* * * *

Commodity	Parts per million
Almond, hulls	0.01
* * * *	* * *
Nut, tree, group 14-12	0.01
* * * *	* * *

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